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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,861	09/30/2005	Charles Roland Wolf	9052-229	6068
20792	7590	05/06/2009	EXAMINER	
MYERS BIGEL, SIBLEY & SAJOVEC			HIRIYANNA, KELAGINAMANE T	
PO BOX 37428			ART UNIT	PAPER NUMBER
RALEIGH, NC 27627			1633	
MAIL DATE		DELIVERY MODE		
05/06/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>		<b>Application No.</b>	<b>Applicant(s)</b>
10/551,861		WOLF ET AL.	
<b>Examiner</b>		<b>Art Unit</b>	
KELAGINAMANE T. HIRIYANNA		1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 27 August 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-28, 34 and 37 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-28, 34 and 37 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/1648)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's response filed on 08/27/2008 in response to office action mailed on 03/27/2008 has been acknowledged.

Claim 1, 11, 26 and 28 are amended.

Claim 37 is new.

*Claims 1-28, 34 and 37 are pending and are examined in this office action.*

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Withdrawn: Claims 1-24 and 34 rejection under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record as set forth in the office action mailed on 03/27/2008 is withdrawn in view of Applicants amendments to cited claims.

Withdrawn: Claims 1-22, and 27-28 rejection under 35 USC 102 (b) as being anticipated by Chaudhuri et al (2001, Gynecologic Oncology 83:432-438) for the reasons of record as set forth in the office action mailed on 03/27/2008 is withdrawn in view of Applicants amendments to cited claims.

Withdrawn: Claims 1-5, 7-9, 13-23, and 27-28 rejection under 35 USC 102 (b) as being anticipated by Lin et al (2001, Int. J. Cancer 91:555-562) for the reasons of record as set forth in the office action mailed on 03/27/2008 is withdrawn in view of Applicants amendments to cited claims.

Withdrawn: Claims 1-5, 7-9, 13-22, and 24-28 and 34 rejection under 35 USC 102 (e) as being anticipated by Risau et al (WO 98/56936) for the reasons of record as set forth in the office action mailed on 03/27/2008 is withdrawn in view of Applicants amendments to cited claims.

#### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

**A person shall be entitled to a patent unless –**

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-28, 34 and 37 are rejected under 35 USC 102 (e) as being anticipated by Vogelstein et al (Patent No: US 6926,890 B2)

The above claims are drawn to a method of monitoring progression of a xenograft in a non human host animal by introducing genetically modified cell with a at least one reporter molecule or gene or agent, allowing said cell to grow and measuring a biochemical or physiological response associated with the reporter molecule or reporter gene.

Regarding claims 1-9, 12-19, 27-28 and 37 Vogelstein teaches monitoring xenograft of SW480 human colon carcinoma cells line derived cells that were genetically

engineered and selected for expressing constructs of a reporter gene Beta-hCG (SW480 CG cell line implanted about  $3 \times 10^6$  cells by subcutaneous injection) in a female athymic (nu/nu) mice and placed them for at least 3 hrs before measurements (entire article; Abstract; col.8, lines 35-38; col.8, lines 45-59). Regarding claims 10 Vogelstein teaches xenograft or more than one cell type and detecting 2 or more) reporters (col.8, lines 16-65 bridging col.9) Regarding claim 11 and 19 Vogelstein teaches quantitative measurements of relationship between tumor burdens and urinary beta-hCG levels or other reporters (col.5 , lines 35-68; col.10, lines col. 9-10; col.4, lines 12-27). Regarding claims 20-22, Vogelstein teaches transcription control of reporter gene under a viral or metallothionein promoter etc., control (col.4, lines 51-65). Regarding claim 24-25 and 34 Vogelstein teaches a post-transcriptional reporting mediated by reported excreted in urine and testing the effects therapeutic agents on various tumors (Abstract; col.10, lines col. 9-10; col.3, lines 1-40; col.6 lines 57-67 bridging col.7). The cited art thus anticipates the invention as claimed.

**Response to Applicants Arguments of 08/27/2008:**

The Applicant argues that Vogelstein only teaches using CMV-hCGB reporter to monitor tumor growth and does not teach determining tumor metabolism.

The Applicants arguments are found not persuasive because Vogelstein clearly teaches regarding using various marker proteins including hCG (col.4, lines 14-27) different promoters for expressing secretable marker expression (example see col.4, lines 44-65). Vogelstein further clearly teaches monitoring products of metabolism such as creatinine and monitoring therapy of transplanted tumors (example see col.8, lines 26; col.10, lines 48-68 bridging col.11). Thus Vogelstein reference addresses all the claim limitations. Hence the rejection is maintained and extended to amended claims and new claims).

*Conclusion:*

No claim allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the

problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

*/Robert M Kelly/  
Primary Examiner, Art Unit 1633*